
# INDUSTRIAL PHARMACY

# G D MEMORIAL COLLEGE OF PHARMACY

| S. No. | Experiment | Date | Page No. | Marks | Teacher's Signature |
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| 1. | To perform preformulation study of given drug.- [Paracetamol / aspirin] | 08/07/022 | 01 to 06 - | 9 | |
| 2. | To prepare cold cream (20gm) | 15/07/022 | 07 to 08 - | 9 | |
| 3. | To prepare vanishing cream (20gm) | 22/07/022 | 09 to 10 - | 9 | |
| 4. | To prepare Calcium gluconate injection (100ml) | 29/07/022 | 11 to 12 | 9 | |
| 5. | To prepare & submit eye drop & eye ointment- | 05/08/022 | 13 to 16 - | 9 | |
| 6. | To perform quality control test of marketed tablets as per IP - | 09/09/022 | 17 to 20 - | 08 | |
| 7. | To prepare ascorbic acid injection - | 16/09/022 | 21 to 23 - | 09 | |
| 8. | To preparation & evaluation of tetracycline capsules | 30/09/022 | 24 to 28 - | 09 | |
| 9. | To preparation & evaluation of aspirin tablets - | 01/10/022 | 29 to 31 - | 09 | |
| 10. | To preparation & evaluation of paracetamol tablets - | 01/10/022 | 32 to 34 - | 08 | |
| 11. | To evaluation of glass container as per IP | 15/10/022 | 35 to 37 - | | |

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|---|---|---|---|---|---|

* Total number of practical = 11
* Total marks of practical = 110
* Total number of practical in present =>
* Total obtained marks =

{# Average marks = Total obtained marks / Total number of practical}

= 8

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⇒ Object :- To perform preformulation study of given drug. [Paracetamol / asprin]-

⇒ Reference : ~~DR~~ SHEIKH A. AIJAZ ~~DR~~., MD RAGEEB MD USMAN, DR. BIYANI R. KAILASH" practical book of industrial pharmacy-1 exclusively marketed & distributed by PV books; edition : 2018 & page number : 01 to 09 -

⇒ Requirement :- a). Chemicals : Paracetamol powder & asprin powder-

b). Apparatus :- Test tubes, pH meter, Funnel, graduated measuring cylinder, stop watch, bulk density apparatus, weighing balance, burette stand, Thiel's tube, thermometer, capillary tube, thread, weighing bottle with stopper, oven, & desiccator.-

⇒ Theory :- → "Preformulation" ←

- It can be defined as an investigation of physical & chemical properties of a drug substance only & when combined with ~~exipi~~ excipients.

* When a newly synthesized drugs shows a sufficient pharmacologic promise in animal model to warrant evaluation in man.-

## ⇒ Approximate solubility ⇐

| Statement of approximate solubility | Approximate volume of solvent in milliliters per gram of solute |
|---|---|
| Very soluble | less than 1 |
| Freely soluble | From 1 to 10 |
| Soluble | From 10 to 30 |
| Sparingly soluble | From 30 to 100 |
| Slightly soluble | From 100 to 1000 |
| Very slightly soluble | From 1000 to 10,000 |
| Insoluble or practically insoluble | More than 10,000 |

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### -: Procedure :-

a) Organoleptic properties :- Check the drug for colour by observing through naked eyes.-
- Take the drug in petridish & observe keenly in day light besides the white & black background.
- Color is generally a function of a drug's inherent chemical structure relating to a certain level of unsaturation.-
- Some compound may appear to have color although structurally saturated.-
- Odor greatly affects the flavor of a preparation or food stuff.-

b) Identification test :- To a glass test tube added 100 mg of drug sample & 10ml of water then added ferric chloride solution. No colour change, remained clear indicate the presence of asprin (acetylsalicylic acid)-

c) Solubility :- Solubility is a physical property of a substance in a particular solvent. It is a necessary parameter to check the drug solubility in various solvents before going to actual formulation step.-

## ⇒ Indication of powder flow properties ⇐

| Flow-Property | Parameters | | |
|---|---|---|---|
| | Carr's index | Hausner's ratio | Angle of repose |
| Excellent | < 10 | 1 - 1.11 | 25-30 |
| Good | 11 - 15 | 1.12 - 1.18 | 31-35 |
| Fair | 16-20 | 1.19 - 1.25 | 36-40 |
| Passable | 21-25 | 1.26 - 1.34 | 41-45 |
| Poor | 26-31 | 1.35 - 1.45 | 46 - 55 |
| Very poor | 32 - 37 | 1.46 - 1.59 | 56-65 |
| Very-very poor | > 38 | > 1.60 | > 66 |

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* As solubility of medicament is directy related with the absorption of drug.- ⇓
* Drug having good solubility dissolved better in the absorption fluid resulting in therapeutic response of it.
* Examination of solubility is an important pre-requisit before actual formulation.-

d> **pH**:- The pH of a solution is very important in the field of solubilisation & stability of drugs, as it must be adjusted in formulation for maximum stability.
* The solution of pH = 7 ⇒ Neutral solution -
* The solution of pH less than 7 = Acidic solution-
* The solution of pH more than 7 = Basic solution-
* The ionic & non-ionic forms of drug depend on the pH of the solution.-
* For measurement of pH, in a glass beaker prepared aqueous solution of drug & measure the pH of solution.

e> **Bulk density**:- It is the weight of powder or granule divided by its volume.-
* Bulk density is used to check the uniformity in bulk powdered materials, to decide the size of container.-

⇒ Calculation :-

Mass = 17gm -

a) Bulk density - Volume = 38ml -

- Bulk density (gm/ml) = $\frac{\text{Weight of sample (W)}}{\text{Bulk volume (V)}}$

= $\frac{17}{38}$ = 0.44 gm/ml -

b) Tapped density :- Mass = 17gm -

Volume = 29ml -

- Tapped density (gm/ml) = $\frac{\text{Weight of sample (W)}}{\text{Tapped volume (V)}}$

= $\frac{17}{29}$ = 0.58 gm/ml.

c) Carr's index -

Carr's index (%) = $\frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$

= $\frac{0.58 - 0.44}{0.58} \times 100$

= $\frac{0.14}{0.58} \times 100$ , = 0.2413 x 100

= 24.13%.

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- Weigh accurately 17gm of drug powder (W). -
- Place it in dried graduated measuring cylinder & note the volume occupied, apparatus for 3 tapping. (V) -
- Calculate the bulk density by using formula -

f) Tapped density :- Weigh accurately 17gm of drug powder (W) -
- place it in dried graduated measuring cylinder & note the tapped volume, apparatus for 100 tapping
- Calculate the tapped density by using formula -

g) Carr's index :- The Carr's index is an indication of the compressibility of a powder. -
- This index is frequently used in pharmaceutics as an indication of the flowability of a powder. -

h) Hausner's ratio :- It is a number that is correlated to the flow-ability of a powder material -
- It is used in wide variety of industries as an indication of flow-ability of a powder. -

i) Angle of repose :- The flow properties of powders are critical for an efficient tableting operation.

d) Hausner's ratio -

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

$$= \frac{0.58}{0.44} = 1.31$$

e) Angle of repose -

$$\left\{ \tan\theta = \frac{h}{r} \right\}$$

where:
$\theta$ = angle of repose -
$h$ = height of pile (cm) -
$r$ = radius of circle (cm) -

$$\left\{ \begin{matrix} h = 4\text{cm} \\ r = 3.7 \end{matrix} \right\}$$

$$\theta = \tan^{-1}\left(\frac{h}{r}\right)$$

$$\theta = \tan^{-1}\left(\frac{4}{3.7}\right) = \tan^{-1}(1.08)$$

$$\theta = 47.2^\circ$$

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* A good flow of the powder to be compressed is necessary to assure efficient mixing & acceptable weight uniformity for the compressed tablets.-
- Take a dry & clean funnel with a round stem of 20-30mm diameter with flat tip.-
- Attach the funnel to the burette stand & on a clean, dry platform place a graph paper sheet below the funnel.-
- Adjust the distance of 4cm b/w the lower tip of funnel & sheet.
- Pour the sample gently in funnel so that a heap of powder forms & touches the lower tip of the funnel.-
- Draw the circle around the heap by using pencil.-
- Measure radius & height of the cone & put value in equation to get the value of angle of repose.-

ii) Melting point :- It is the temperature at which a solid becomes a liquid at normal atmospheric pressure.-
- It is an identity for pure crystalline organic compounds.-
- Take a capillary tube & at one end seal it by applying flame for a very short time.-
- Added a small quantity of drug powder (3-5mg) from another side.

⇒ Observation table for performulation study on asporin drug -

| Test | Observation |
|---|---|
| Colour - | -White crystalline powder |
| Odour - | - Odorless |
| Taste - | : Bitter tast - |
| Identification taste - | No colour change |
| Solubility with water - | Slightly soluble (0.33 gm/100ml) |
| pH - | 3.5 |
| Bulk density - | 0.44 gm/ml - |
| Tapped density - | 0.58 gm/ml - |
| Hausner ratio - | 24.13 % |
| Angle of repose - | 1.31 |
| Melting point - | 47.2° |
| | 138°c |

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- Tie the capillary tube containing sample with thermo-meter near its bulb with thread.-
- Added the liquid paraffin in Thiel's tube & immerse the thermo-meter with capillary tube into liquid paraffin
- Care should be taken so that thread should not come in contact with liquid paraffin & rate of heating should not be more than 3°c/minute.-
- Apply heat to the Thiel's tube with the help of burner & carefully record the temp. at which solid drug compound converts to liquid.-
- Repeat the procedure twice & note down the readings carefully.-

⇒ Result :-

Preformulation studies of asporin drug was observed completed.-

Date 15/07/022

S. No. 02 Page No. 07

⇒ Object :- To prepare of cold cream (20gm) -

⇒ Reference :- Gaud R.S. & Gupta G.D. "Pharmaceutics practical book published by Satish kumar Jain, 1st edition : 2002 , Page number : 32 -

⇒ Requirement - (A) Chemicals - Cetyl esters wax, white wax, mineral oil, sodium borate etc.-

(B) Apparatus - Beaker, measuring cylinder, glass stirring rod, water bath & weigh balance etc -

⇒ Theory - Cold cream is a water-in-oil emulsions.-
- Creams are semisolid dosage forms.-

* Application of cold cream avoids aggravation of skin problems during the cold season.-
* Cold cream is primarily used to prevent excessive drying of skin.-
* It has emollient action & prevents dehydration of skin.-
* The key chemical constituent of cold cream is bees wax.-
* Cold cream is mainly used for skin treatment, due to its moisturizing properties.-

=> Formula – (20gm) -

| Ingredients | Quantity given (gm) | Quantity taken (gm) |
|---|---|---|
| • Cetyl esters wax - | 12.5 gm | 2.5 gm |
| • White wax - | 12.0 gm | 2.4 gm |
| • Mineral oil - | 56.0 gm | 11.2 gm |
| • Sodium borate - | 0.5 gm | 0.1 gm |
| • Purified water | 19.8 gm | 3.8 gm |
| | Total = 100 gm | Total = 20 gm |

=> Calculation –

$$\text{Taken quantity (x) gm} = \frac{\text{Given quantity}}{\text{Total amount}} \times \text{Preparation amount}$$

eg. - Cetyl esters wax = $\frac{12.5}{100} \times 20 \Rightarrow 2.5$ gm -

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=> Procedure – Reduce size of cetyl esters wax & white wax in small pieces. -

- Melt them on a steam bath with the mineral oil & continue heating until temp. of the mixture reaches 70°C (A). -
- Dissolve the sodium borate in purified water & heat at 70°C in separate flask -
- Gradually added aqueous solution (B) to the mixture of oily phase (A) with continues & rapid stirring until it has congealed. –

=> Category - Emollient & cleansing cream. -

=> Storage – Preserve in a well-closed container. -

=> Instruction – For external use only. -
- Not for ophthalmic, oral, or intra-vaginal use -

=> Result :- Cold cream was prepared & submitted. -

Date..22/07/022

S. No.....03..... Page No.....09.....

⇒ Object:- To preparation of vanishing cream (20gm)-

⇒ Reference:- Gaud R.S. & Gupta G.D." pharmaceutics practical book published by Satish kumar jain, 1st edition: 2002; page number: 33-

(A) Chemicals-

⇒ Requirements:- Stearic acid, stearyl alcohol, cetyl alcohol, methyl paraben, propyl-paraben, potassium hydroxide & purified water etc-

(B). Apparatus-

- Beaker, measuring cylinder, glass stirring rod, water bath & weigh balances etc-

⇒ Theory:-

- A cream is a preparation usually for application to the skin.-
- Creams are semi-solid emulsions of oil & water.-
- Vanishing creams get their name from the fact that they seem to disappear when spread on the skin.-
- It is also known as foundation cream which are applied to skin to provide a smooth emollient base before the application of face powder & other face make up.-

* Formulation – [Formula] - (20gm) -

| Ingredients | Quantity given (gm) | Quantity taken (gm) |
|---|---|---|
| · Stearic acid - | 13 gm. | 2.6 gm - |
| · Stearyl alcohol - | 1.0 gm - | 0.2 gm - |
| · Cetyl alcohol - | 1.0 gm - | 0.2 gm - |
| · KOH (potassium hydroxide) - | 0.90 gm. | 0.18 gm - |
| · Methyl paraben - | 0.10 gm - | 0.02 gm |
| · Propyl paraben | 0.05 gm - | 0.01 gm |
| · Purified water (Q.S.) | 83.95 gm. | 16.79 gm |

* Formula ⇒ $\frac{\text{Given quantity}}{\text{Total amount}} \times$ Prepare quantity -

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- Chemically they are oil in water emulsions consisting of stearic acid, an alkali, a polyol & water.-
- One important constituent of the cream is "hydroquinone".-

⇒ Procedure -

- melt stearic acid, stearyl alcohol & cetyl alcohol at 75°c in a conical flask. (A).
- Dissolve potassium hydroxide in purified water at 75°c in another conical flask & added preservative. (B).
- Added (A) into (B) at 75°c slowly with continuous stirring.-
- Slowly stir the mixture unit a smooth cream was formed at room temperature.-

⇒ Category :- Vanishing cream-

⇒ Storage :- Store in well closed container, in cool place. Do not freeze.-

⇒ Instruction - For external use only. Not for Opthalmic, Oral, or intravaginal use.-

⇒ Result :- Vanishing cream was prepared & submitted.-

Date. 29/07/2022.

S. No. 04 Page No. 11

* Object:- To prepare Calcium gluconate injection [100ml]-

* Reference- "Gaud R.S. & Gupta G.D." pharmaceutical book published by satish kumar jain, 1st edition: 2002; page number: 153 to 154.-

* Requirement - (A.) Chemicals-

- Calcium gluconate, Calcium-D-saccharate & water for injection etc.-

(B.) Apparatus- Beaker, measuring cylinder, syringe, needle, ampoules, Whatman filter paper /membrane filter, autoclave.-

* Theory:- Calcium is the most abundant cation & the 5th most common inorganic element in the human body.-
* Calcium is essential for the maintenance of the nervous muscular & skeletal systems, & for cell membrane & capillary permeability.-
* Its role in bone structure & muscle contraction is well known, but $Ca^{2+}$ is also important for blood

⇒ Formula -

| Ingredient | Given quantity | Taken quantity |
|---|---|---|
| 1. Calcium gluconate - | 5.0 gm | 5.0 gm |
| 2. Calcium-D-saccharate- | 1.75 gm | 1.75 gm |
| 3. Water for injection | Q.S. to 100 ml | 100 ml (Q.S.) |

⇒ Taken quantity =

[∵ Formula-] ⇒ $\frac{\text{Given quantity}}{\text{Total amount}}$ × Prepare quantity -

eg.- Calcium gluconate ⇒ $\frac{5.0}{100} \times 100$ ⇒ 5.0 gm.

- Calcium-D-saccharate ⇒ $\frac{1.75}{100} \times 100$ ⇒ 1.75 gm.
- Water for injection ⇒ $\frac{100(q.s)}{100} \times 100$ ⇒ 100 ml (Q.S.)

Date 29/05/2022

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Coagulation, nerve conduction & electrical conduction in the myocardium.-

* Calcium gluconate is calcium salt of gluconic acid, an oxidation product of glucose.-

* Procedure- All glassware were sterilized by the autoclave at 121°C for 15 minutes.-

- Weigh accurately calcium gluconate & Calcium D-saccharate.-
- Dissolve calcium gluconate in water for injection in a beaker with application of heat then added Calcium D-saccharate to it.-
- Adjust the pH in between 6-8 with 10% NaOH sodium.-
- keep the solution for cooling.-
- After cooling filter the ~~sol~~ solution through Whatman filter paper / 0.45 µm membrane filter to remove of any particulate matter.-
- Fill the prepared injection in conical flask with the help of measuring cylinder.-
- Seal the conical flask by aluminium foil paper.-
- Sterilized the conical flask by autoclaving at 121°C for 30 minutes.-

* Result:- Calcium gluconate injection was prepared & submitted successfully.-

Date... 05/08/2022

S. No..... 05 Page No..... 13

* Object - To prepare & submit eye drop & eye ointment-

# Reference - "Gaud R.S. & Gupta G.D." pharmaceutics practical book published by Satish kumar jain, 1st edition: 2002, page number: 130, 131 & 142-

# Requirement -

(A) 'Chemicals' -

i) Solution for eye drops -

• Methyl hydroxybenzoate, Propyl hydroxybenzoate, purified water -

ii) Zinc sulphate eye drop -

• Zinc sulphate, sodium chloride & solution for eye drops q.s. to -

iii) Eye ointment -

• Wool fat, Yellow soft paraffin & Liquid paraffin q.s. to -

(B) Glassware -

• Beaker, glass stirring road, measuring cylinder, spatula, heating mental, autoclave & aseptic rooms-

# formula -

⊙ Solution for eye drops - (50ml)

| "Ingredient" | "Given quantity" | Taken quantity |
|---|---|---|
| ⊙ Methyl hydroxy benzoate | 22.0 mg | 11.0mg |
| ⊙ Propyl hydroxy benzoate | 11.4 mg | 5.7mg |
| ⊙ Purified water, sufficient to Produce - | 100.0ml (q.s.) | 50ml (q.s) |

# Taken quantity = $\frac{\text{Given Quantity}}{\text{Total amount}}$ x Prepare quantity

eg. - Methyl hydroxy benzoate = $\frac{22}{100} \times 50$ = 11.0 mg -

- Propyl hydroxy benzoate = $\frac{11.4}{100} \times 50$ = 5.7mg -

- Purified water (q.s.) = $\frac{100}{100} \times 50$ => 50ml (q.s.) -

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# Theory :- i). "Solution for eye drops" - (50ml) -

- Solution for eye drops must be freshly prepared aseptically & dispensed in previously sterilized containers. -

ii). Zinc Sulphate eye drop - (10ml) -

- Opthalmic preparations are sterile products, free from foreign particles. -
- Aqueous eye drops contain suitable anti-microbial preservatives.

*. Eye drops are sterile aqueous / oily solutions / suspension. -

⊙ Examples of eye drops - Zinc sulphate eye drop, Framycetin eye drop, Pilocarpine eye drop, Silver nitrate eye drop. -

iii). Eye ointment - (20gm)

- Eye ointments must be free from large particles & should be prepared under aseptic condition. -
- Opthalmic ointments are help to improve ocular bioavailability & sustain the drug release. -

⊙ Example of eye ointment - Chloramphenicol ointment, tetra-cycline ointment & Hydro-cortisone ointment -

# Formula -

⊙ Zinc sulphate eye drop - (10ml)

| "Ingredient" - | "Given quantity" | Taken quantity |
|---|---|---|
| ⊙ Zinc sulphate - | 12.5 mg - | 25.0mg |
| ⊙ Sodium chloride - | 40.0 mg - | 80.0mg |
| ⊙ Solution for eye drops q.s. to | 5.0ml (q.s.) | 10.0ml (q.s) - |

# Taken quantity = $\frac{\text{Given quantity}}{\text{Total amount}}$ x Prepare quantity

eg. zinc sulphate = $\frac{12.5}{5} \times 10 \Rightarrow$ 25.0mg -

· Sodium chloride = $\frac{40}{5} \times 10 \Rightarrow$ 80.0mg -

· Solution for eye drops (q.s.) = $\frac{5}{5} \times 10 \Rightarrow$ 10ml (q.s.) -

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# Procedure - All glass-ware were sterilized by the auto-clave at 121°C for 15 minutes. -

⇓

i:- Solution for eye drops - (50ml) -

· Dissolve methyl hydroxy-benzoate & propyl hydroxy-benzoate in boiling water under aseptic condition. -

· Added freshly boiled & cooled purified water to produce the required volume. -

ii:- Zinc sulphate eye drop - (10ml) -

· Dissolve weighed amount of zinc sulphate in purified water with aseptic condition. -

· Dissolve sodium chloride in small amount of purified water -

· Added this solution & mix if required filter it aseptically condition. -

iii:- Eye ointment - (10gm) -

· Melt together weighed amount of wool fat & yellow soft paraffin in a container -

· Added liquid paraffin to make up weight 10gm. -

# Formula-

⊙ "Ointment eye" - (20 gm)

| ⊙ "Ingredient" | ⊙ "Given quantity" | Taken quantity |
|---|---|---|
| ⊙ ~~Zinc Sulphate~~ - | | |
| ⊙ Wool fat | 1.0 gm | 2.0 gm |
| ⊙ Yellow soft paraffin - | 8.0 gm | 16.0 gm |
| ⊙ Liquid paraffin, sufficient to produce - | q.s. 10 gm - | 20 gm (q.s.) |

# Taken quantity = $\frac{\text{Given quantity}}{\text{Total amount}}$ × Prepare Quantity

eg.- Wool fat = $\frac{1.0}{10} \times 20$ = 2.0 gm -

· Yellow soft paraffin = $\frac{8.0}{10} \times 20$ = 16.0 gm -

· Liquid paraffin (q.s) = $\frac{10}{10} \times 20$ = 20 gm (q.s.) -

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· Filter the hot mixture through coarse filter paper placed in a heated funnel.-

· Filtrate was sterilized by dry heat at 150°c for sufficient time to ensure that the whole was maintained at this temperature for one hours.-

· Allow to cool at room temperature without opening the container.-

# Results -

· Eye drop & eye ointment were prepared & submitted.-

Date 09/09/022

S. No. 06 Page No. 17

# Object :-

- To perform quality control test of marketed tablets as per IP-

# Reference :-

- "Indian pharmacopoeia-2010" published by the indian pharmacopoeia commission Ghaziabad (U.P.), 6th edition effective from 1st September : 2010, page number : 187-193 (Volume-1st) & 751 - 754 (Volume-2nd)

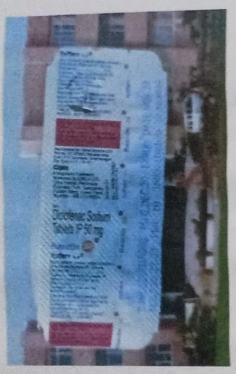
# Requirement :-

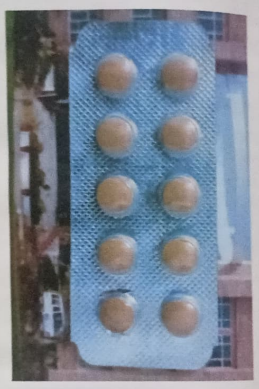
(A.) Chemicals-

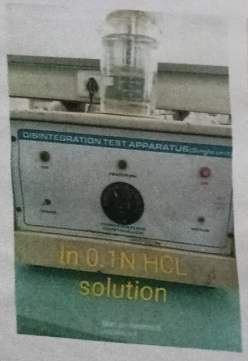
- Tablets, 0.1N Hydrochloric acid (HCl), phosphate buffer at pH 6.8 [Potassium dihydrogen phosphate & disodium hydrogen phosphate] etc-

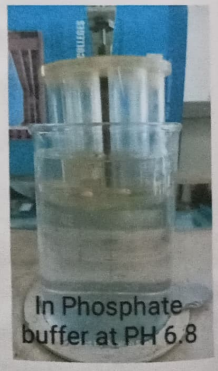
(B.) Apparatus-

- friability apparatus, Disintegration apparatus (Basket-rack assembly), volumetric flask, Beaker, measuring cylinder, Weigh balances & Whatman filter paper, monsanto hardness tester / pfizer hardness tester & Vernier Caliper etc-



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# Theory :- # Tablets #

- Tablet is a solid unit dosage form.-
- The solid unit ~~solid~~ dosage form of medicament/medicaments with suitable excipients-
- * Tablets are intended for oral administration.-
- Tablets are prepared by the "compression method" are called compressed tablets.-
- * Tablets ⇒ Circular in shape, Biconvex/flat in shape-

## Qulaity Control test # (Quality)-

* marketed tablet test (Finished product test)-

i> Dis-integration test/Disintegrating test -

- This test is not used for "chewable & sustain release" tablets-

ii> Uncoated tablets ⇒ water, NMT - 15 minutes-

iii> Film coated tablets ⇒ water, NMT - 30 minutes-

iv> Coated tablets ⇒ water, NMT - 60 minutes

v> Enteric coated tablets ⇒ In 0.1M Hcl solution operate "without the discs" for 2hrs ⇓

- No tablets shows signs of cracks/no change in tablets-

⇓

- At pH 6.8 phosphate buffer solution operate "with discs"

⇓

# Description #

- 7×4 mm, Round shape, biconvex → Enteric coated tablets-
- Yellow to light brown colour

* Average weight ⇒ 0.169 gm - (169 mg)
* Diameter = 7mm-
* Thickness = 4mm-
* Hardness = 15 kg/cm² -
* Friability test = NA
* Disintegration time = In 0.1M HCl solution for 2 hrs
  Volume 900ml & temp. 37°C ± 2°C
  ⇓
  After 2hrs no change in tab.-
  ⇓
  At PH 6.8 phosphate buffer solution. Volume 900ml & 37°C ± 2°C
  ⇓
  NMT 60minutes

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v) Dispersible tablets ⇒ 24°C to 26°C, NMT - 3 minutes -
* Uniformity of dispersible tab. ⇒ 2 tablets in 100ml water ⇒ 24hour
  ⇓
  # 22 diverse-
vi) Effervescent tablets ⇒ 20°C to 30°C, 1 tablet in 250ml water, NMT - 5 minutes
vii) Soluble tablets (Coated / film coated) ⇒ 15°C to 25°C, NMT - 3 minutes -

ii) Dissolution test -
- The test is studied for a tablets & capsule -

* Apparatus as per IP ⇒ Paddle (1st) & Basket (2nd) → 75 rpm, 900ml
* Apparatus as per USP ⇒ Basket (1st) & Paddle (2nd) & 37°C -

iii) Content of active ingredient (Assay) - ± 10%
- 10 tablets crass ⇒ 1 tablet blender ⇒ Dilution & absorption -

iv) Content uniformality test -
- Each individual tablet less than 10mg drugs or < 10% drugs -

v) Hardness - used apparatus - * monsanto hardness tester -
* Pfizer & Stanlab tester -

# Procedure -
- Put one tablet into each tube, suspend the assembly in the beaker containing 0.1M HCl & operate without the discs for 2 hrs. (hours) -

# "Observation table"

* Diclofenac sodium tablets IP 50mg *
* B.No.: C20RDA048 -

| S. No. | Tablets | Weight (gm) | Diameter (cm) | Thickness (cm) | Hardness |
|---|---|---|---|---|---|
| 1. | Tablet-I | 0.176 gm | 0.7cm | 0.4cm | |
| 2. | Tablet-II | 0.174 gm | 0.7cm | 0.4cm | .15 kg/cm² |
| 3. | Tablet-III | 0.171 gm | 0.7cm | 0.4cm | |
| 4. | Tablet-IV | 0.163 gm | 0.7cm | 0.4cm | |
| 5. | Tablet-V | 0.168 gm | 0.7cm | 0.4cm | |
| 6. | Tablet-VI | 0.166 gm | 0.7cm | 0.4cm | |

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- Unless otherwise stated in the individual monograph.-
- Remove the assembly from the liquid.-
- No tablet shows signs of cracks that would allow the escape of the contents or disintegration, apart from fragments of coating.-
- Replace the liquid in the beaker with mixed phosphate buffer pH 6.8, add a disc to each tube & operate the apparatus for further UMT 60minutes.-

# Result

- Quality control test of marketed tablet (Diclofenac sodium tablets IP 50mg) as per IP was observed.

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# Object:-

To prepare ascorbic acid injection (20ml)-

# Reference-

· "DR. Kailash R. Biyani, MD. Rageeb MD. Usman, DR. Aijaza A. Shetkh" practical book of industrial pharmacy-1st published by Pee Vee, Edition: 2018, page number: 59-62- & Gaud & Gupta-Page number-151-

# Requirement:-

(A) Chemical-

· Ascorbic acid, Disodium EDTA, Sodium hydroxide, Sodium bicarbonate & water for injection q.s. -, propylene glycol-

(B) Apparatus-

· Beaker, measuring cylinder, syringe, needle. amber colour ampoules, membrane filter, pH meter & weigh balance etc-

# Theory- # Ascorbic acid #

· Ascorbic acid (Vitamin-C) is a water-soluble vitamin.-

· It occurs as a white or slightly yellow crystal or powder with a light acidic taste.-

# formula-

· Ascorbic acid injection - (20ml) -

| Ingredients · | Given quantity · | Taken quantity · |
|---|---|---|
| · Ascorbic acid - | 1.03 gm · | 0.41 gm - |
| · Sod. bicarbonate - | 2.47 gm · | 0.98 gm - |
| · Propylene glycol - | 2.50 gm - | 1.00 gm - |
| · Sod. hydrosulphite - | 0.25 gm · | 0.1 gm · |
| · Disod. edetate | 0.05 gm | 0.02 gm |
| · water for injection (Q.S.) | 50.0 ml (Q.S.) | 20 ml (Q.S.) |

* Taken quantity = $\frac{\text{Given quantity}}{\text{Total amount}}$ × Prepare quantity/amount) -

· Ascorbic acid = $\frac{1.03}{50}$ × 20 = 0.41 gm -

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· It is an anti-scorbutic product -

· The chemical name of ascorbic acid is L- ascorbic acid. -

* Ascorbic acid injection is a clear, colorless to slightly yellow sterile solution of ascorbic acid in water for injection for i.v., i.m. & subcutaneous used & contains no preservatives. -

# Procedure -

· The formulation must be carried out in clean area. -

· Weigh the ascorbic acid accurately. -

· Dissolve ascorbic acid slowly under constant stirring & nitrogen bubbling -

· Added sod. bicarbonate & slow stirring. -

· Separately prepare solution of sodium hydrosulphite in small proportion of water for injection & added in the solution -

· Added solution of disodium edetate & mix uniformly -

· Added mix propylene glycol with slow stirring. -

· pH is adjusted to 5.5 to 6.5 using sod. hydroxide solution or ascorbic acid solution -

· make up the volume & mix with water for injection. -

- Sodium bicarbonate = $\frac{2.97}{50} \times 20 = 0.988$ gm -
- Propylene glycol = $\frac{2.50}{50} \times 20 = 1.00$ gm -
- Sodium hydrosulphite = $\frac{0.25}{50} \times 20 = 0.1$ gm -
- Disodium edetate = $\frac{0.05}{50} \times 20 = 0.02$ gm -
- Water for injection (Q.S.) = $\frac{50}{50} \times 20 = 20$ ml (Q.S) -

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- Sterilized by passing through sterilized 0.22 µ membrane filter into sterilized filling vessel. —

# Result -

- Ascorbic acid injection ampoules were prepared & submitted. —

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# Object :-

· Preparation & evaluation of capsules - (Tetracycline capsules = 250mg) -

# Reference -

· DR. Shekh Aijaz, DR. Kailash "industrial pharmacy - 1st practical book published by Pee Dee.; Edition : 2018 & page number - 43 to 52. -

# Requirement -

· Chemical - Tetracycline hydrochloride, Dried starch & Dried talcum -

· Apparatus -

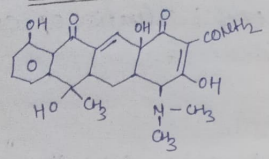
· Mortar & pestle, empty capsules, sieve, hand operated capsule filling machine, volumetric flask, pipette, beaker, stop watch, measuring cylinder, Whatman filter paper & DS integration test apparatus -

# Theory - "CAPSULES"

· Capsules are solid dosage form in which drugs is enclosed in hard gelatin capsule shell -
- in soft soluble shell of gelatin -

* Various shapes & capacities -

# Tetra-cycline #



- Colour - Yellow -
- Odour - Odourless -
* Crystalline powder -
- Soluble - water, acid & alkali -
- Insoluble - Chloroform & ether -

* It is stable in air -
- But exposure to strong sunlight causes it to darken. -

* These are readily absorbed & bound to plasma protein in varying degrees -

# Uses - It is a prescription antibiotic -
- Treat a wide range of infections -
  eg. - Skin infection -
  - Respiratory tract infection -
  - Genital & urinary infection -

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# Preparation of tetracycline capsules -

## Procedure #

- Weigh the required quantity of drug & excipients -
- Moisture content should be less than 1.5%. -
- Starch should be dried & sieved through # 100, moisture less than 1.5%. -
- Talcum should be dried & sieved through # 100, moisture less than 1%. -
- Mix all the ingredients uniformly using mortar & pestle. -
- Empty capsule shells of number "0" is selected & for filling the content in capsule shell hand operated capsule filling machine is used. -

⇓

- This machine consist of a bed, a loading tray, a powder tray, a pin plate, a sealing plate having a rubber top, a lever, a cam handle. -

⇓

- The empty capsules are filled in the loading tray & it is placed over the bed. -

⇓

- The cam handle is operated to separate the capsule caps from their bodies. -

⇓

# Formula-

| Ingredient | Given quantity | Taken quantity |
|---|---|---|
| · Tetracycline Hcl - | 250 mg - | 208.33 mg - |
| · Dried starch - | 25 mg - | 20.83 mg - |
| · Dried talcum - | 25 mg - | 20.83 mg - |

# · Taken quantity = $\frac{\text{Given quantity}}{\text{Total quantity}}$ × Prepare quantity

· Tetracycline Hcl = $\frac{250}{300} \times 250$ = 208.33 mg

· Dried starch = $\frac{25}{300} \times 250$ = 20.83 mg -

· Dried talcum = $\frac{25}{300} \times 250$ = 20.83 mg

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- The powder tray is placed in a proper position & filled with an accurate quantity of powder with scraper -
- The excess of the powder is collected on the platform of the powder tray -
- The pin plate is lowered & the filled powder is pressed by moving the pin downwards.
- After pressing the pin plate was raised & the remaining powder was filled into the bodies of the capsules
- The powdered tray was removed after its complete filling -
- The cap holding tray was again placed in position -
- The plate with the rubber top was lowered & the lever was operated to lock the caps & bodies -
- The loading tray was then removed & filled capsules are collected. -
- Capsules were store in air tight container -

# Evaluation of tetracycline Capsules-

i) Weight variation/uniformity of weight test-

- 20 capsules are used individually weigh & calculate avg.-
- Average weight of capsule ⊙% deviation/variation wt.- Contents
- < 300mg = 10%.
- ≥ 300mg = 7.5%.

ii) Disintegration test - (HCl) - • Water (medium) -

• Operate the apparatus for 30 minutes.

iii) Content of active ingredients - (Assay) - ± 10% -

- This range is based on the requirement that 20 Capsules are used in the assay.-

* NLT 5- Capsules are used.-

iv) Uniformity of content -

• This test is applicable to Capsules that active ingredient contain less than 10mg / 10% w/w -

* For capsules-

·Containg more than one active ingredient

· Test for each active ingredient that corresponds to the afore-mentioned conditions-

* 10 capsules taken at random -

⇓

· NMT 1- individual values outside the 85%- 115%-

· Not any individual values outside the 75%- 125%-

⇓

· If 2/3 individual value are outside 85%- 115%-

⇓

· 20- capsules another taken (Total = 30 capsules (10+20))-

· NMT 3- individual values outside the 85%- 115%-

· Not any individual values outside 75%- 125%-

# Result :-

· Tetracycline capsules were prepared & evaluated-

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09/10

# Object-

· To preparation & evaluation of asprin tab.- (75mg - 20tabs)

# Referenle-

· "DR. Shekh Aijaz, DR. kailash" industrial pharmacy-1st practical book published by Pee vee.- Edition: 2018 & page number: 23-32-

# Requirement-

(A) Chemical-

· Asprin, micro crystalline cellulose (mcc- Avicel PH-102), Cros-Carmellose sodium, Tale & magnesium stearate-

(B) Apparatus-

· Single punch tablet machine, weight balance, mortar & pestle, spatule & sieves #40, #44, #60 & #100-

# Theory-

· Aspirin or acetylsalicylic acid is a derivative of salicylic acid.-

· Aspirin is a non-steroidal anti-inflammatory drugs (NSAIDs)-

# Formula - [1 tab. = 150mg, so 20 tab × 150 = 3000mg]

| Ingredient | Given quantity | Taken quantity |
|---|---|---|
| - Aspirin - | 75mg - | 1.5gm - |
| - microcrystalline cellulose (Avicel) | 52.5mg - | 1.05gm - |
| - Croscarmellose sodium - | 7.5mg - | 0.15gm - |
| - Tale - | 7.5mg - | 0.15gm - |
| - magnesium stearate - | 7.5mg - | 0.15gm - |

- Taken quantity = $\frac{\text{Given quantity}}{\text{Total amount}}$ × Preparation amount

i) Aspirin = $\frac{75}{150} \times 3000 =$ 1500mg | 1.5gm -

ii) MCC ⇒ $\frac{52.5}{150} \times 3000 =$ 1050mg | 1.05gm -

iii) Croscarmellose sodium = $\frac{7.5}{150} \times 3000 =$ 150mg | 0.15gm -

iv) Tale = $\frac{7.5}{150} \times 3000 =$ 150mg | 0.15gm -

v) magnesium stearate = $\frac{7.5}{150} \times 3000 =$ 150mg | 0.15gm -

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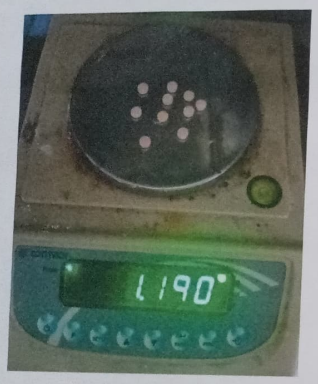
# Procedure - [By direct compression method) -

- Weigh the required quantity of aspirin & other excipients -
- Pass the aspirin drugs & other excipients through #40/44 & mixed for 15 minutes -
- mixed thoroughly all the excipients with granular aspirin in mortar with the help of spatula in order to get uniform distribution of ingredients -
- Pass the tale & magnesium stearate through #60 - mixed uniform distribution of ingredients for 2 minutes
- The granules are ready for compression & can be compressed into tablets -

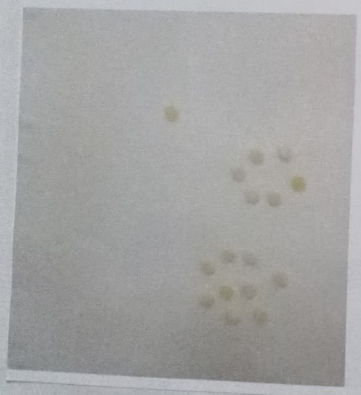
# Evaluation of aspirin tablets -

i) Weight variation - 20 tablets used for test -

| ⊙ Weight | ⊙ % variation |
|---|---|
| ⊙ ≤ 80mg - | 10%. |
| ⊙ >80mg - <250mg - | 7.5%. |
| ⊙ ≥ 250mg - | 5%. |







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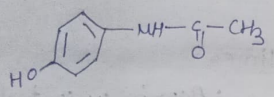
② Friability test - Weigh ≥ 6.5 gm/7 gm -
- 25 rpm & 4 minutes ⇒ 100 rotation -
• Weight ⇒ weight loss NMT 1% -

③ Disintegration time -
• Uncoated tablets -
• Aspirin uncoated tablets -
Water, NMT - 15 minutes -

④ Hardness -
• The hardness of a tablet is an indication of its strength.
- Depending upon the type & conc. of the binding agent the hardness of tablet varies. -
* The force is measure in $kg/cm^2$ -

# Result -
• Aspirin tablets was prepared & evaluated. -

# Paracetamol # [Acetaminophen-]




* White or almost white-
* Crystalline powder-

* Standard (IP)-

· PCM tablets contain not less than 95% & not more than 105% of the stated amount of PCM ($C_8H_9NO_2$)-

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# Object-

· To preparation & evaluation of paracetamol tablets (500mg)-

# Reference-

· "DR. Shekh Aijaz, DR. Kailash" industrial pharmacy-1st practical book published by Pee Vee. Edition: 2018 & page number: 12 to 22-

# Requirement-

Ⓐ Chemicals-

· Paracetamol, microcrystalline cellulose (MCC), Cros-carmellose sodium, Poly-vinyl-pyrrolidone (PVP), Tale, magnesium stearate & purified water-

Ⓑ Apparatus-

· Weigh balance, single punch tablet machine, mortar & pestle, measuring cylinder, beaker, sieves #40/44 & #60- & dryer-

# Theory-

· Paracetamol was discovered in 1877.-

· PCM may inhibit the nitric oxide (NO) pathway mediated by a variety of neurotransmitter receptors.-

# formula - [1 tab - 800 mg, so, 20 tab = 16,000 mg] -

| Ingredient | Given quantity | Taken quantity |
|---|---|---|
| Paracetamol - | 500 mg - | 10 gm - |
| microcrystalline cellulose - | 180 mg - | 3.6 gm. - |
| croscarmellose sodium - | 40 mg - | 0.8 gm - |
| Poly vinyl pyrolidone - (k-30) | 40 mg - | 0.8 gm - |
| Tale | 20 mg - | 0.4 gm - |
| magnesium stearate - | 20 mg - | 0.4 gm - |
| Purified water | Q.S. (10ml) | Q.S. (10ml) - |

. Taken quantity = $\frac{\text{Given quantity}}{\text{Total amount}}$ x Prepare amount -

i) PCM = $\frac{500}{800} \times 16{,}000 = 10{,}000$ mg | 10 gm -

ii) MCC = $\frac{180}{800} \times 16000 = 3600$ mg | 3.6 gm -

iii) Croscarmellose sod. = $\frac{40}{800} \times 16{,}000 = 800$ mg | 0.8 gm -

iv) PVP = $\frac{40}{800} \times 16{,}000 = 800$ mg | 0.8 gm -

v) Tale = $\frac{20}{800} \times 16{,}000 = 400$ mg | 0.4 gm -

vi) mag. stearate = $\frac{20}{800} \times 16{,}000 = 400$ mg | 0.4 gm -

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# Procedure - [By Wet granulation] -

1st • Weigh the required quantity of Paracetamol & other all excipient -

2nd. Paracetamol, microcrystalline cellulose & croscramellose sodium were passed through sieve # 40/44 & mixed for 15 minutes -

3rd. Poly vinly pyrolidone (k-30) was dissolved in 10 ml purified water -

4th. step-2nd materials were granulated with step-3rd binder solution with "continous kneading" -

5th. step-4th materials were passed through sieve # 10 -

6th. step-5th materials was dry at 60°c for 20 minutes in dryer -

7th. step-6th materials was passed through sieve # 40/44

8th. Tale & magnesium stearate was passed through sieve # 60 & mixed with step-7th material for 5 minutes -

9th. The granules are ready for compression & can be compressed into tablets -

# ~~Weight~~ Evaluation of Paracetamol tab -

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① Weight variation - 20 tab. used for test -

| Weight | % variation |
|---|---|
| - ≤ 80mg | 10%. |
| - > 80mg - < 250mg | 7.5%. |
| - ≥ 250mg | 5%. |

② ~~Friability test~~ - Dis integration time -

· PCM uncoated tablets -

· Uncoated tab -

- Water, NMT - 15 minutes -

③ Friability test -

· Weigh ≥ 6.5 gm | 7 gm

- 25 rpm & 4 minutes => 100 rotation -
- Weight => weight loss NMT 1% -

④ Hardness - The hardness of a tablets is an indication of its strength. -

- Depending upon the type & conc. of the binding agent the hardness of tablet varies -

* The force is measure in $kg/cm^2$ -

# Result -

· Paracetamol tablets was prepared & evaluated. -

Date. 15/10/022

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# Object :-

Abstract evaluation of glass container as per I.P.-

# Reference -

"DR. Shekh Aijaz, DR. Kailash" industrial pharmacy-I practical book published by Pee Vee.- Edition : 2018 & page number : 95 to 99 -

# Requirements -

(A.) Apparatus -

· Beakers, measuring cylinder, measuring cylinder, & autoclave etc-

(B.) Chemicals -

· Acetone & sulphuric acid -

# Theory -

· Glass is employed as the container material of choice for most of pharmaceutical products.-

· Glass containers are evaluated by USP tests powdered glass test & water attack test-

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* Types of glass-
  - Type-I : Boro-silicate glass-
  - Type-II : Sodalime treated glass-
  - Type-III : Sodalime glass-
  - Type-IV : NP general purpose sodalime glass not for parenterals-

# Procedure-

* Powdered glass test-

- Step-1: Preparation of glass specimen-

  · Few containers rinsed thoroughly with purified water & dried with stream of clean air, grind the containers in a mortar to a fine powder & pass through sieve no. #20 & #50.-

- Step-2: Washing the specimen-

  · 10 gm of the above specimen is taken into 250ml conical flask & wash it with 30ml acetone.-

  · Repeat the washing, decant the acetone & dried after which is used within 48 hrs.-

# Powder glass test -

| Types of glass | Amt. of titrant Consumed (ml) |
|---|---|
| Type - I | 0.1 ml |
| Type - II | 8.5 ml |
| Type - IV | 15 ml |

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- Step-3 -
  - 10 gm of sample is added with 50ml of high purify water in 250 ml flask.-
- Place it in an autoclave at 121°c for 30min.-
- Cool it under running water. Decant the solution into another flask, wash again with 15ml distilled water & again decant.-
- Titrate immediately with 0.02N sulphuric acid using methyl red as an indicator & record the volume.-

# Result :-

- Glass containers were passed the test as per IP.-